

**REMARKS**

In an Office Action dated January 23, 2004, claims 1-20 and 22-24, all of the claims under consideration in the above-identified application, were rejected. In addition, the drawings were objected to, as was claim 22. In response to the Office Action, Applicants are amending the claims and adding new Figs. 6 and 7. In view of the amendments and the following remarks, Applicants respectfully request reconsideration of this application, and allowance of all of the presently pending claims, as amended.

The drawings were objected to as not showing every feature of the invention specified in the claims. In response thereto, schematic Figs. 6 and 7 are being added. Fig. 6 shows the prior art configuration described on page 3, lines 25-28 of the specification as originally filed. This prior art configuration utilizes a separate hemostatic barrier 26, a chondrocyte-charged matrix 28 all covered by a separate patch 30. In contrast, the present invention avoids the necessity of providing a separate hemostatic barrier 26, as shown in Fig. 7.

New Figs. 6 and 7 merely schematically illustrate what is described in the specification. Thus, no new matter is being added. In view of the amendment to the drawings, withdrawal of the rejection to the drawings is respectfully requested.

Claim 22 is objected to as being of improper dependent form. Claim 22 has been amended to correct the dependency to claim 1. Accordingly, withdrawal of the objection to claim 22 is respectfully requested.

Claims 1-20, 22 and 24 were rejected under 35 USC §112, second paragraph, as being indefinite in use of the term "separate" in claim 1. It is respectfully pointed out that while the multi-layer sheet of collagen membrane material specified in claim 1 includes two individual layers, the claim does not specify that the layers are separate, which means separated or apart. Instead, claim 1 specifies that the multi-layer sheet is fixed over a damaged area without application of a separate hemostatic barrier layer in the area.

Production of a multi-layer membrane without “separate” layers, *i.e.*, layers that are separated or apart, is described at page 10, paragraph 0051 of the specification as filed.

In view of the above, withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claims were rejected under 35 USC §103(a) as being unpatentable over Stone et al. U.S. Patent No. 5,624,463 in view of Pachence et al. WO 96/24310. Insofar as this rejection could apply to the claims, as amended, it is respectfully traversed.

Stone et al. discloses a prosthetic threaded scaffold which is screwed into a joint injury. The threaded scaffold of Stone et al. clearly is not a “sheet” as required by the present claims. Moreover, Stone et al. fails to provide any hint or suggestion of utilizing a multi-layer “sheet” of collagen membrane material as specified in the present claims. In order to further define the multi-layer sheet of collagen membrane material utilized in the present invention, the claims are being amended to recite that the barrier layer has a thickness of about 0.2-2mm and the matrix layer of the multi-layer sheet has a thickness of about 0.2-12mm.

The Pachence et al. reference cannot be combined with Stone et al. to suggest the present invention.

Pachence et al. discloses an implant for repair of defects in cartilage, including a dense collagen membrane 14 oriented toward the defect, and a porous collagen matrix 13 oriented away from the defect. This is precisely the opposite configuration as specified in the present claims. Thus, Pachence et al., when combined with Stone et al. leads away from the present invention.

In view of the above remarks, withdrawal of the rejection based on Stone et al. in combination with Pachence et al. is respectfully requested.

Claims 8 and 9 were rejected under 35 USC §103(a) as being unpatentable over Stone et al. in view of Pachence et al., and further in view of Sonis WO 90/13302. Claims 10 and 11 were rejected under 35 USC §103(a) as being unpatentable over Stone

et al. in view of Pachence et al., and further in view of Caplan et al. US Patent No. 5,197,985. Claims 13 and 14 were rejected under 35 USC §103(a) as being unpatentable over Stone et al. in view of Pachence et al., and further in view of Geistlich et al. U.S. Patent No. 5,573,771. Claim 17 was rejected under 35 USC §103(a) as being unpatentable over Stone et al. in view of Pachence et al., and further in view of Seid US Patent No. 5,254,133. Claims 7, 12 and 22 were rejected under 35 USC §103(a) as being unpatentable over Stone et al. in view of Pachence et al., and further in view of Geistlich et al. WO 95/18638. Insofar as these rejections could apply to the claims, as amended, they are respectfully traversed.

The above discussion concerning the deficiencies of the Stone et al./Pachence et al. combination is equally applicable here and incorporated herein by reference. None of the Sonis, Caplan et al., Geistlich et al. '771, Seid or Geistlich et al. '638 references supply the above-noted deficiencies of the Stone et al./Pachence et al. combination. In view thereof, withdrawal of the rejections based on Stone et al., Pachence et al. and Sonis, Caplan et al., Geistlich et al. '771, Seid or Geistlich '638 is respectfully requested.

Applicants submit that the present application is now in condition for allowance. Reconsideration and favorable action are earnestly requested.

Respectfully submitted,

By



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